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K040064

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510(k) Summary

NEW medical Technology

NewMedical Technology, Inc

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Date of Submission: December 10 , 2003

Submitted by: Haitham Matloub,
Senior Engineer, Research and Development

The micro distractor/external fixator introduced by *NewMedical Technology, Inc.*, is a device which is substantially equivalent to other marketed external fixators /distractors. Its indications for use are substantially the same, that is, external fracture fixation and/or distraction. The *NewMedical Micro Distractor/External Fixator* described here is completely identical to the NewMedical Micro Bone Distractor/Fixator that has already been approved by the (FDA/Dental Devices Committee) for use in external fixation of mandibular fractures or for mandibular distraction, referring to *NewMedical Technology, Inc.* product (**K030485).**

The main advantages over other marketed devices from other vendors include its' smaller profile and lightweight construction. The recessed distraction actuating screw is tamper resistant and hence better for use in pediatric patients. The device can only be actuated with the use of a custom actuator which is provided in the kit with the device. Hence, this tamper resistant design is useful when the device is used as an external bone fixation device for the treatment of fractures. Similarly, the conversion to a static from a dynamic fixator does not require any adjustment or addition of parts. The alloy metals used provide for excellent stability.

In summary, the features incorporated into the *NewMedical Micro Distractor/External Fixator* have specific advantages over other substantially equivalent products to enhance ease of placement along with the care and comfort of the patient requiring external fixation/distraction of the mandible or small bones. Neither one of the above features will raise any safety concern because they don't change any of the basic design concepts compared to other similar approved devices.

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Equivalence To Marketed Devices:

Equivalency of the *NewMedical Micro Distractor/Fixator Device,* is based on similarities in intend use, materials, design and operational principles to the predicate external distractor /fixation devices.
The design features of the *NewMedical Micro Distractor/Fixator Device,* and the named predicate devices are substantially equivalent as these devices attach to bone and move the bone outward when mechanical distraction forces are applied. In addition to moving bones, the *NewMedical Micro Distractor/ Fixator Device,* is substantially equivalent to the named derives in stabilizing fractured bone structures.

1-Intended Use:

All of the named devices, and the *NewMedical Micro Distractor/Fixator Device,* are intended to be used as external fixation/ distraction devices for the stabilization/lengthening of bone and bone fragments.

2-Materials:

The materials used in the manufacturing of the *NewMedical Micro Distractor/Fixator Device,* are two grades of Stainless steel. The material conforms to ASTM F 138-97. Gold plating and Electro polishing are applied to all device components. Stainless steel and gold materials have long history of successful clinical usage. Stainless steel is used in the manufacture of the *Hoffman Mini Fixator, Synthes Mini-Lengthener* and the *Hand Bone Lengthener.*

Lengthening screw Stainless Steel 316L/gold plating
Locking set screws: SS 18-8/gold plating
Guide rods (rails) SS 316L/Gold plating
Body SS 316 L/Gold plating

3- Design:

The basic design features of the *NewMedical Micro Distractor/Fixator Device* are substantially equivalent to the predicate devices. The subject device and the named derives accept various diameter pins. The subject device and the named devices operate using the same principle by utilizing screw mechanism that the surgeon adjusts to control the distraction/compression length. The subject device and the predicate devices use clamps attached to the distraction screw for holding the pins or threaded wires. Distraction/compression occurs by turning the screw shaft clockwise or counter clockwise causing attached clamps to slide along the axial axis of the screw shaft.

Lengthening screw Stainless Steel 316L,

Locking set screws: SS 18-8/gold
Guide rods (rails) SS 316L
Body SS 316 L

4- Operational Principles:

The basic operational principles for the named device and the subject device are similar – mainly in site preparation, pin placement and device operation. The bone distraction/compression is similar also.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2004

Mr. Haitham Matloub
Senior Engineer, Research and Development
NewMedical Technology Inc.
N.14 W.23833 Stone Ridge Drive
Suite G100 (Mail Box # 1)
Waukesha, Wisconsin 53188

Re: K040064
Trade/Device Name: NewMedical Micro Bone Distractor/Fixator
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: KTT
Dated: December 23, 2003
Received: February 18, 2004

Dear Mr. Matloub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040064

Device Name: NewMedical Micro Bone Distractor/Fixator

Indications For Use: indicated for use for pediatric as well adult Metacarpal-Phalangeal fractures. For external fixation of hand fractures or for distraction of osteotomies for the purpose of distraction osteogenesis as fractures.

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040064

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)